REMARKS

This responds to the Office Action dated 17 April 2009. Claims 1, 7, 13, 21, 24, 30 and 31 are amended above. The amendments are supported by at least FIGS. 6-14 and the related description of those figures in the present application. No new matter has been added. Claims 1-18, 21, 22, and 24-31 remain pending in the application.

Claim Objection

The Examiner objected to claim 1 on minor formal grounds. Claim 1 has been amended to remedy the formality issue.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 3-7, 11-18, 21, 22 and 24-29 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,136,010 to Modesitt et al. Applicants respectfully traverse this rejection.

Claim 1 recites "a suture configured to move with the first needle from the retracted position to the extended position; a snare configured to move with the second needle from the retracted position to the extended position." Claim 7 recites "a snare configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel, the snare comprising a loop portion; a suture and a needle combination configured to be inserted through the wall of the blood vessel at another location that is adjacent to the opening." Claim 13 recites "inserting a snare into the vessel on a first side of the vessel opening, the snare comprising a loop portion; inserting a needle with a suture into the vessel on a second side of the

vessel opening." Claim 21 as amended recites "the vascular closure device is configured to pass the loop portion of the snare through a wall of the blood vessel at a first location on the wall spaced laterally of a tissue puncture, pass the suture and the needle through the wall of the blood vessel at a second location on the wall spaced laterally of the tissue puncture, and then pass the suture and needle into the loop portion." Claim 24 recites "inserting a needle and a suture together through a wall of the blood vessel at a location that is adjacent to the opening; inserting a snare through the wall of the blood vessel at another location that is adjacent to the opening."

Modesitt discloses an example treatment method with reference to FIGS. 11A-E. The closure device used in this method includes first and second needles 38, 38'. The needle 38' includes a length of suture 34 that has a barbed end 42 connected at a distal end thereof. The needle 38 also includes a barbed end 42. The foot 24 includes a short suture 74 pre-mounted thereto with fittings 40 connected at free ends of the short suture 74. The fittings are pre-positioned in needle receptacles at opposite ends of the foot 24. The short suture 74 and the fittings 40 are carried by the foot 24 (which is carried, in turn, by a shaft 12) and are clearly not carried by either of the needles 38, 38'. Thus, while the suture 34 is movable with the needle 38' from a retracted position (*see* FIG. 11A) to an extended position (*see* FIG. 11C), the fittings 40 are not carried by either of the needles 38, 38', but are instead carried by the foot 24. Further, the short suture 74 and fittings 40 are inserted through the tissue tract TT and puncture P of the vessel V, while the needles 38, 38' are inserted through a wall of the vessel at separate locations adjacent to the tissue tract TT and puncture P.

Therefore, Modesitt fails to disclose "a suture configured to move with the first needle from the retracted position to the extended position; a snare configured to move with the second needle from the retracted position to the extended position," as required by claim 1, for at least the reason the fittings 40 are not carried by either of the needles 38, 38'. Modesitt fails to disclose "a snare configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel, the snare comprising a loop portion; a suture and a needle combination configured to be inserted through the wall of the blood vessel at another location that is adjacent to the opening," as required by claim 7, "inserting a snare into the vessel on a first side of the vessel opening, the snare comprising a loop portion; inserting a needle with a suture into the vessel on a second side of the vessel opening," as required by claim 13, "the vascular closure device is configured to pass the loop portion of the snare through a wall of the blood vessel at a first location on the wall spaced laterally of a tissue puncture, pass the suture and the needle through the wall of the blood vessel at a second location on the wall spaced laterally of the tissue puncture, and then pass the suture and needle into the loop portion," as required by claim 21, and "inserting a needle and a suture together through a wall of the blood vessel at a location that is adjacent to the opening; inserting a snare through the wall of the blood vessel at another location that is adjacent to the opening," as required by claim 24 for at least the reason that the fittings 40 are inserted through the tissue tract TT and puncture P, rather than through the wall of the vessel at other locations.

Therefore, Applicants submit that Modesitt fails to disclose every limitation of claims 1, 7, 13, 21 and 24, and the claims that depend from them. Applicants respectfully request allowance of these claims.

Claim Rejections – 35 U.S.C. § 103

Claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,562,688 to Riza in view of U.S. Patent No. 5,330,488 to Goldrath, and further in view of U.S. Patent No. 5,562,684 to Kammerer. Applicants respectfully traverse this rejection.

As noted above, claim 1 as amended recites both "a suture configured to move with the first needle from the retracted position to the extended position," as well as a "snare configured to move with the second needle from the retracted position to the extended position, the snare comprising a loop portion configured to grasp the suture after the first and second needles are in the extended position and the first needle and suture extend within the loop portion of the snare."

In each of Riza, Goldrath and Kammerer, one or both of the suture and snare features (as identified by the Examiner) are advanced through the needles after the needles have been positioned in the extended position. There is no teaching or suggestion in any of the references of advancing the suture and snare features with the needles. At least some of the references disclose using a single needle for use with both the suture and snare. For example, Riza discloses, with reference to FIG. 5 in the description at column 7, lines 37-57, that the introducer needle 82 is first inserted into the recess 68 along with the first end 85 of the suture 81, and then later inserted through the recess 69 with the wire loop 84. In Goldrath, the snare 32 is passed into the surgical site through a previously placed trocar 30. A suture material 20 is threaded through the needle 40 and guided by an angled guide of the open end of the needle for grasping by the snare 32 (*see* column 5, lines 20-32 of Goldrath). Riza and Goldrath also fail to disclose positioning a needle and suture within a loop portion of a snare. In both Riza and Goldrath, the

suture alone passes through what the Examiner has identified as a snare feature. Kammerer fails to disclose every feature of claim 1 for similar reasons.

The Examiner asserts that the "configured to" limitations of claim 1 are not positive limitation but only require the ability to so perform. Applicants respectfully disagree. The Examiner cites *In re Hutchison*, 69 USPQ 138 for support of his assertion. In re Hutchison addresses the term "adapted to", which is a much less definite term that does not connote the positive limitation associated with the term "configured to". Applicants submit that the limitations "a suture configured to move with the first needle from the retracted position to the extended position," as well as a "snare configured to move with the second needle from the retracted position to the extended position, the snare comprising a loop portion configured to grasp the suture after the first and second needles are in the extended position and the first needle and suture extend within the loop portion of the snare," recited in claim 1 are affirmative features of the claimed vascular closure device that define what is required, not simply the capability of the device.

In view of the above, Applicants submit that Riza, Goldrath and Kammerer, alone or in combination, fail to disclose, suggest, or render obvious every limitation of claim 1, and the claims that depend from it.

Claims 7-10 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,728,114 to Evans et al. Applicants respectfully traverse this rejection.

Claim 7 as amended recites "an anchor configured to extend through an opening in a blood vessel, ...a snare configured to be inserted through a wall of the blood vessel at a location that is adjacent to the opening in the blood vessel, ...[and] a suture and needle combination

configured to be inserted through the wall of the blood vessel at a location that is adjacent to the opening, the loop portion of the snare also being configured to receive the suture needle combination after the snare and the suture and needle combination are inserted through the wall of the blood vessel and to grasp the suture in the blood vessel."

In contrast, Evans discloses features that are neither positioned in nor interact within the blood vessel. For example, the sealing mask 22 disclosed by Evans is positioned within the skin layer of the arterial puncture track 10A and does not extend through the opening 10B in the wall 10C of the artery. Therefore, the sealing mask 22 is not positioned within the vessel. Furthermore, the loop distal end 42 of the carrier filament 30 is operable to grasp the extending portions 24A, 24B of suture 24 at a location outside of the puncture 10 and then positioned within the apparatus 20, but is not configured "to be inserted through a wall of the blood vessel" (*i.e.*, through the opening 10B in the wall 10C of the artery). The suture 24 does not interact with the loop portion 42 "in the blood vessel," as required by claim 7. Nor does the loop portion 42 "retract the suture through the wall of the blood vessel," as required by claim 7.

There is no teaching or suggestion provided by Evans of a vascular closure device that includes all of the features recited in claim 7. Further, the Examiner has not given adequate weight to the "configured to" limitations recited in claim 7 for at least those reasons discussed above related to claim 1. The "configured to" limitations of claim 7 are not merely recitations of functions the claimed device has the ability to perform, but actual positive limitations of the device and should therefore be given patentable weight.

In view of the above, Applicants submit that Evans fails to disclose, suggest, or render obvious every limitation of claim 7 and the claims that depend from it.

Claim 30 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,722,981 to Stevens in view of U.S. Patent No. 5,562,684 to Kammerer, and further in view of U.S. Patent No. 6,638,286 to Burbank et al.

Claim 30 as amended recites "a suture configured to move with the first needle from the retracted position to the extended position; a snare configured to move with the second needle from the retracted position to the extended position, . . . the suture and first needle being positionable inside the wire loop of the snare after the first and second needles move to the extended position;

wherein the wire loop grasps the suture after the first needle is removed from inside the wire loop."

Stevens shows in FIGS. 7A-C that the suture 121 is advanced through the needle 112 after the needle 112 has been positioned in the vessel. Furthermore, there is no disclosure or suggestion by Stevens of positioning the needle 112 and suture 121 "inside the wire loop of the snare," or "the suture and first needle being positionable inside the wire loop of the snare after the first and second needles move to the extended position," as required by claim 30. FIGS. 7A-C of Stevens clearly show advancing the suture 121 alone through the loop 119. Further, Stevens fails to disclose or suggest "the wire loop grasps the suture after the first needle is removed from inside the wire loop," as further required by claim 30, for at least the reason that the needle 112 is never positioned in the loop 119.

Kammerer and Burbank fail to remedy the deficiencies of Steven as it relates to claim 30. Kammerer is used only for the disclosure of a suture with a pre-tied knot. Burbank discloses a ligation device 100 having a position loop 124 carried by an advancing element 134, and a

snaring element 136 that extends into the loop 124. However, there is no suture associated with the snaring element 136 to provide "the suture and first needle being positionable inside the wire loop." Furthermore, there is no disclosure or suggestion by Burbank of "the wire loop grasps the suture after the first needle is removed from inside the wire loop," as further required by claim 30, for at least the reason that there would be no suture to grasp by the loop 124 if the snaring element 136 were removed from within the loop 124.

Therefore, Stevens, Kammerer, and Burband, alone or in combination, fail to disclose, suggest, or render obvious every limitation of claim 30. Claim 30 should thus be allowable.

Claim 31 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,496,332 to Sierra et al. in view of U.S. Patent No. 5,562,684 to Kammerer. Applicants respectfully traverse this rejection.

Claim 31 as amended recites "inserting a snare into the vessel at a first location laterally adjacent to the vessel opening, the snare including a wire loop; inserting a suture with a needle into the vessel at a second location laterally adjacent to the vessel opening; inserting the suture with the needle into the wire loop after inserting the snare and the suture with the needle into the vessel."

Sierra discloses advancing a mesh member 34 through the primary vessel opening/puncture. There is no teaching or suggestion by Sierra of inserting the mesh member 34 into the vessel at a location "laterally adjacent" to the primary vessel opening. Kammerer fails to remedy the deficiencies of Sierra as it relates to claim 31. Therefore, Sierra, alone or in combination with Kammerer, fails to disclose, suggest, or render obvious every limitation of claim 31. Claim 31 should thus be allowable.

Conclusion

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If there remain any unresolved issues, Applicants invite the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Applicants expressly disclaim all arguments, representations, and/or amendments presented or contained in any other patent or patent application, including any patents or patent applications claimed for priority purposes by the present application or any patents or patent applications that claim priority to this patent application. Moreover, all arguments, representations, and/or amendments presented or contained in the present patent application are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application.

Respectfully submitted,

Date 17 JULY 2009

By _____
L. Grant Foster
Registration No. 33,236